UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Subcategory Docket: 06-CV-11337
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, No. 07-CV-11618-PBS	)	Judge Patti B. Saris
	)	Magistrate Judge Marianne B. Bowler

ABBOTT LABORATORIES INC.'S REPLY IN SUPPORT OF MOTION TO DISMISS FOR LACK OF SUBJECT-MATTER JURISDICTION UNDER THE FALSE CLAIMS ACT'S PUBLIC DISCLOSURE BAR

Dated: December 4, 2009

James R. Daly
Eric P. Berlin
Tara A. Fumerton
JONES DAY
77 West Wacker Drive, Suite 3500
Chicago, Illinois 60601
Telephone: (312) 782-3939
Facsimile: (312) 782-8585

Counsel for Defendant Abbott Laboratories Inc.

In its opening brief, Abbott identified documents that predated Ven-A-Care's complaint, yet clearly publicly disclosed the same allegations that AWPs for Abbott's Ery drugs were inflated to the extent alleged in the complaint, and Abbott, like many other pharmaceutical manufacturers, was marketing AWP spreads to gain market share. For example:

- Spreads for Abbott's Erys were widely reported.
  - In 1984, the HHS-OIG reported spreads on Abbott's E.E.S.® 400 tabs of 56% (Ex. 2 at 10.203).
  - In 1991, as to Abbott's Ery-Tab® 250 mg. the OIG reported a spread of 124% between prices in Canada and *the HCFA FUL* (1991 OIG Report "Comparison of Reimbursement Prices for Multiple-Source Prescription Drugs in the United States and Canada, attached hereto as Ex. 25).
  - In 1992, testimony to Congress reported spreads on Abbott's E.E.S.® 400 tabs, E.E.S.® liquid, Ery-Tab®, Erythrocin® and Pediazole® suspension of 125-632% – equal to or larger than the spreads alleged in VAC's complaints (Ex. 11 at 302-310).
  - In 1998 and 1999, Myers & Stauffer, one of Ven-A-Care's experts in this case, reported spreads of 190% on Ery-Tab® and of 280% for multi-source drugs that had a MAC price, including Ery-Tab® (Exs. 16, 17).
  - Many Public reports disclosed average spreads between pharmacies' average acquisition costs and AWPs. The average spreads reached 280% for generic drugs with MACs in the late 1990s (Ex. 14) and 194% for multi-source drugs generally by 2001 (Ex. 17). There also were widely recognized spreads much larger than these averages. (Ex. 12 at 3; Ex. 14 at 4; Ex. 16 at 5.)
- Repeatedly throughout the 1980s and 1990s, public documents accused pharmaceutical manufacturers, *including Abbott*, of "playing games with AWPs" to use them as a "marketing tool" to "play the spread" in order "to gain market share" from pharmacies seeking greater Medicaid payments. (Exs. 12, 13, 18; *see also* Exs. 3, 4, 5, 6, 15.)

Unable to dispute the public disclosures' content, Ven-A-Care claims that each one is not quite good enough: that some are too early, some are not specific enough, and some were not distributed widely enough. The law, however, does not support Ven-A-Care, and does not permit a relator to avoid the import of the disclosures taken as a whole. *See, e.g., Dingle v.*

Bioport Corp., 388 F.3d 209, 214 (6th Cir. 2004) ("The fact that the information comes from different disclosures is irrelevant."); *United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 174 n.8 (5th Cir. 2004) (multiple sources "considered as a whole").

Having admitted that it first discovered its allegations in the second half of 2000 (Ex. 21 at 20:11-21:15, 22:16-23:9, 49:2-4), Ven-A-Care is unable to claim legitimately or with any force that it was an original source of these previously disclosed allegations. Ven-A-Care's allegations were based not on "direct and independent knowledge," as required by the FCA. Ven-A-Care never purchased, sold, or submitted a Medicaid claim for any of the Ery drugs, and has no personal knowledge that Abbott marketed the spread on these drugs. Instead, Ven-A-Care merely conducted collateral research of price lists that were widely available. (Combined Opposition ("Comb. Opp.") at 9 (reviewed "price information, such as wholesaler pricing data").) Ven-A-Care relies heavily on its self-proclaimed status as an industry insider (even though it had not seen a patient for half a decade by the time it filed these claims against Abbott, but the First Circuit recently rejected this as a valid basis for standing. *United States ex rel. Ondis v. City of Woonsocket*, No. 08-2389, --- F.3d ---, 2009 WL 3838803, at *9 (1st Cir. Nov. 18, 2009) ("If a relator merely uses his or her unique expertise or training to conclude that the material elements already in the public domain constitute a false claim, then a qui tam action cannot proceed."). Ven-A-Care was not an original source of the allegations in this case. Moreover, Ven-A-Care, as a corporation, legally cannot be an original source under the FCA's express terms.

Ven-A-Care is simply not a proper *qui tam* relator in this case, and this Court has no subject-matter jurisdiction to entertain Ven-A-Care's claims. They must be dismissed.

I. THE ALLEGATIONS IN VEN-A-CARE'S COMPLAINT ARE BASED UPON PUBLIC DISCLOSURES.

A. The Alleged Inflation Of AWPs For The Ery Drugs Was Publicly Disclosed Before Ven-A-Care Brought Its Complaint.

There is no doubt that public disclosures – which began as early as sixteen years before VAC notified the government of its allegations and continued through the 1990s and 2000s– revealed the very spreads on the Ery drugs about which Ven-A-Care began to complain in 2001. (Exs. 2, 11, 14-17.) Ven-A-Care argues that the public disclosures were too early or not specific enough or do not technically qualify as public disclosures under the FCA for one reason or another. Not one of Ven-A-Care's arguments holds water.

Ven-A-Care's claim that some public disclosures were too early is legally unsupported and nonsensical. With this argument, Ven-A-Care would have this Court believe that the public thought that spreads were reduced some time after the mid-to-late 1980s due to unspecified changes to Medicaid regulations in 1987 (Comb. Opp. at 21), but Ven-A-Care cites no evidence for this, and the record shows the opposite. (*See* Ex. 2 (1984 OIG report showing spreads up to 56%); Ex. 14 (1997 OIG report showing spreads of 135%; 2002 OIG Report "Actual Acquisition Cost of Generic Prescription Drug Products, attached hereto as Ex. 26 (showing spreads of 194%).)

Ven-A-Care's argument that some disclosures were too general fares no better. Ven-A-Care relies on *United States ex rel. Ven-A-Care v. Actavis Mid-Atlantic, LLC*, 2009 U.S. Dist. LEXIS 92945 (D. Mass. Oct. 2, 2009), in which the Court ruled that a report was not a public disclosure because it discussed "average prices" in "generalized industry-wide terms." *Id.* at

*10-11, *14-15. Here, however, Abbott has identified public disclosures discussing the specific Ery drugs at issue in this case and the spreads alleged by Ven-A-Care. (Exs. 2, 11, 16, 17.)[1]

Responding to that important distinguishing point, Ven-A-Care claims that the Ery drugs listed in the identified public disclosures may not have been Abbott's Erys and that the word "fraud" was not used. Neither argument has merit. The drugs listed were Abbott trade-named Erys. (Ex. 27, United States Patent and Trademark Office Search Results.) Ven-a-Care does not contest this point from the Meditz affidavit. (Ex. 1.) (VAC Resp. at 4.) Regardless of Ven-A-Care's nit-picking of other aspects of the Meditz affidavit, the Erys listed in the documents could not have been referring to anything other than the Abbott Erys, and anyone with any knowledge of these drugs (as a relator would be expected to have) would have known that.

Even if the listed drugs could not so easily have been identified as Abbott's Erys, Ven-A-Care's argument would still fail. The law is clear that a public disclosure need not mention an alleged wrongdoer by name. It is enough if it "'set[s] the government squarely on the trail of fraud,' such that it would not have been difficult for the government to identify [the defendant] as a potential wrongdoer." *In re Pharm. Indus. AWP Litig.*, 538 F. Supp. 2d 367, 383 n.10 (D. Mass. 2008). For instance, in *In re Natural Gas Royalties Qui Tam,* 562 F.3d 1032 (10th Cir. 2009), the relator sued 220 defendants in the natural gas industry, alleging misconduct relating to the calculation of royalties due to the government. Prior to the relator's complaint, however, Senate documents were published that described similar misconduct within that industry. *Id.* at 1039. Despite the fact that the Senate documents did not identify all alleged bad actors by name,

[1] Abbott respectfully disagrees with the Court's opinion that the reports finding large average spreads based on invoices for drugs across the industry are not public disclosures. Such industry-wide findings put the government on the trail of the alleged fraud. For example, if a person learns that the bank accounts at his or her bank have been reduced by an average of 42.5%, surely that person will check if his or her account was impacted. Claiming otherwise suggests that the government could have ignored the OIG's findings, but that clearly cannot be, and was not, the case. Furthermore, the 1997 OIG report in fact did include an Abbott Ery drug (Ex. 15.)

the Tenth Circuit found that they were sufficient to put the government on the trail of the fraud and to allow the government to "target its investigation toward specific actors and a specific type of fraudulent activity." *Id.* at 1042. Thus, the documents constituted an invalidating public disclosure, undermining relator's case.

The Tenth Circuit's rationale is even more applicable here. The disclosures referred specifically to Abbott's trademarked drugs. For example, the 1984 OIG Report listed E.E.S. 400®, a federally registered trademark of Abbott. (Ex. 27.) There were only a handful of manufacturers of the erythromycin drugs when the disclosures were made. When Abbott's Ery-Tab® 250 mg was listed in the 1991 OIG Report, there were only approximately five other manufacturers of erythromycin tablets. (Ex. 28, 1991 Redbook excerpt.) Even if the Court were to accept that the Erys in the reports were not identifiable as Abbott's Erys, there can be no doubt that the reports detailing the alleged inflation of AWP for those drugs were more than sufficient to put the government "on the trail" of this alleged fraud and to target this select group of companies. The documents therefore constitute public disclosures.[2] *See also United States v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1019 (9th Cir. 1999) (finding industry-wide disclosures sufficient for a "narrow class of suspected wrongdoers - local electrical contractors who worked on federally funded projects over a 4-year period"); *United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 687 (D.C. Cir. 1997) (finding industry-wide disclosures sufficient "where the subject was easily identifiable federal employee organizations that provide vending services on federal property").

[2] Even Ven-A-Care does not contest that the "based upon" element of the public disclosure bar would be met by these reports. A relator's allegations are "based upon" a public disclosure when they are "similar to, supported by, or the same as those that have been publicly disclosed regardless of where the relator obtained his information." *In re Pharm. Indus. AWP Litig.*, 538 F. Supp. 2d 367, 377-79 (D. Mass. 2008). Ven-A-Care's allegations regarding the alleged AWP inflation of the Erys mirror the public disclosures' findings.

Ven-A-Care's attempt to brush aside the public disclosures because they do not use the word "fraud" also fails. For example, while Ven-A-Care concedes that Ex. 16 "actually mentions an Abbott Ery product," Ven-A-Care (alluding to the *Springfield Terminal* standard) protests that the report did not "provide the necessary 'Z'." (VAC Resp. at 12.) The argument falls short both factually and legally. First, several of the documents alleged fraud as closely as they could without using the word. (*See, e,g.,* Ex. 10 ("AWP has become an exploited figure"); Ex. 3 ("artificially high AWP prices").) Furthermore, because Ven-A-Care has argued that these spreads alone are fraudulent (Ex. 21 at 92:11-93:10; 97:20-98:15; 105:5-20), documents revealing the spreads about which Ven-A-Care now complains suffice as disclosures of fraud under Ven-A-Care's own standard.

Second, the argument relies on a misreading of *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994). The *Springfield Terminal* test is disjunctive – a public disclosure bars a relator's claims if it reveals *either* X (allegedly false facts) + Y (true facts) *or* Z (the allegation of fraud). *Springfield Terminal*, 14 F.3d at 654. The whole point of *Springfield Terminal* is that "fraud" (Z) need not be mentioned by name in order for public disclosures of X and Y to trigger the bar. *See United States ex rel. Settlemire v. District of Columbia*, 198 F.3d 913, 919 (D.C. Cir. 1999) (relator is barred where there has been a public disclosure of a fraudulent transaction, even without the specific allegation of fraud). Because the documents identified in this motion plainly disclose both X and Y, no more is required.

Ven-A-Care's additional gripes about particular documents are equally without merit:

- With respect to the 1992 NARD testimony and price lists (Ex. 11), Ven-A-Care belabors the point that the prices for the E.E.S.® 400 tabs, E.E.S.® 200 liquid, E.E.S,® 400 liquid, Ery-Tab® (200 mg, 333 mg, 500 mg), and Pediazole® suspension submitted by NARD to Congress in 1992 were not available to the NARD pharmacies. Ven-A-Care claims incorrectly, however, that the contract prices were available only to hospitals, even though Mr. Rector from NARD

testified that the prices were available to "purchasers, *including* hospitals," and he referred to "pharmacies." (Anderson Dec. Ex. 9 at 295-96.) Ven-A-Care even cites a portion of the record where Mr. Rector states that the prices were available to "many other for-profit pharmacies."[3] Citing no evidence with respect to Prucare's operations in the early 1990s, Ven-A-Care's assertions about Prucare are unsupported and immaterial. At a minimum, these Ery spreads disclosed to Congress would have put the government on the trail of the alleged fraud.

- Ex. 15 is comprised of the OIG Office of Audit Services' working papers that included invoices for Ery drugs. Ven-A-Care challenges their authenticity, but the DOJ produced them and represented that they were the working papers for the 1997 OIG report.

- Exs. 16 and 17 (the 1998 and 1999 Idaho and Wyoming Myers & Stauffer reports) found spreads on Ery-Tab® similar to those alleged by Ven-A-Care. Ven-A-Care argues that state reports do not count as public disclosures under the FCA. While this issue is unsettled,[4] significant case law favors Abbott's position. *See, e.g., United States ex. rel. Bly-Magee v. Premo*, 470 F.3d 914, 917-18 (9th Cir. 2006); *Battle v. Board of Regents*, 468 F.3d 755, 762 (11th Cir. 2006); *Hays v. Hoffman*, 325 F.3d 982, 987 (8th Cir. 2003).

Ven-A-Care claims that one of its allegations – "that the FUL program was not protecting the United States from drug manufacturers' false, inflated prices" – was not publicly disclosed (Comb. Opp. at 7), but that simply is not true. (*See, e.g.*, Ex. 25 (Comparison of Reimbursement Prices For Multiple-Source Prescription Drugs in the United States and Canada); Exs. 14 & 17.) Additionally, the allegations follow from the discussion of spreads in other disclosures. All of the allegations about the Ery drugs' spread were publicly disclosed prior to Ven-A-Care filing its complaint.

[3] Abbott agrees that Mr. Rector indicated that the contract prices were not available to the NARD members; clearly, however, the prices were available to other pharmacies in the market, and Ven-A-Care's vituperative accusations of Abbott hiding a page and lying to the Court are misplaced. Indeed, Abbott used a complete copy Mr. Rector's testimony before Congress in many depositions including the Rule 30(b)(6) deposition of Ven-A-Care in this case. (SOF Reply ¶ 29.)

[4] The U.S. Supreme Court recently heard argument on this issue. Oral Argument, *Graham County Soil & Water Conservation District v. United States ex rel. Wilson*, No. 08-304 (U.S. Nov. 30, 2009).

B. The Alleged "Marketing The Spread" Activity Was Publicly Disclosed Before Ven-A-Care Brought Its Complaint.

As noted in Abbott's opening brief, allegations about pharmaceutical companies, including Abbott, "marketing the spread" were publicly disclosed at least in 1986, 1987, 1989, 1996, 1997, and 1998. (Exs. 3, 4, 5, 6, 12, 13, 15, 18.) Ven-A-Care's various attempts to escape the import of these public disclosures all fail.

The 1986 Colorado Medicaid letter to HCFA (Ex. 3) warned that pharmaceutical manufacturers were using artificially high AWP prices as a "marketing tool." Ven-A-Care argues that a letter to a federal agency, even in the course of an administrative investigation and when the letter was indisputably received by the federal government, cannot count as a public disclosure under the FCA. As stated with respect to Exs. 16 and 17 (*supra*, pp. 6-7), significant law rejects Ven-A-Care's position, and this situation is more compelling than the one presented by the record in *Graham County*.

The 1987 *Lexington Herald*'s front page exposé (Ex. 4) revealed that "many" companies, referring to the industry as a whole, were "exaggerating [AWP] as a sales technique" and "playing the spread." It broadcast the very "scheme" that Ven-A-Care would weave into its complaint fourteen years later. Whether or not this particular article revealed "the true prices and false prices" is irrelevant because one article need not cover all of Ven-A-Care's allegations; the public disclosures must be considered in the aggregate. (*See* case law cited, *supra*, p. 2.) Nor can VAC defeat the public disclosure bar by claiming, without any support, that this article was "little-noticed," a standard invented by VAC with no basis in law. And even this Ven-A-Care does not get right – the article was noticed enough that the OIG cited it in its 1989 report. (Ex. 5 at 5.) Finally, Ven-A-Care concedes that the article "constituted some disclosure of possible fraud similar to the later alleged by VAC." (Comb. Opp. at 20-21.) That the article was,

according to Ven-A-Care, "equivocal at best as to whether the conduct it was describing was simply a by-product of the AWP system or likely fraud" does not nullify the disclosure.

A public disclosure must reveal the conduct; it need not call the conduct fraud, particularly when it is highly contested whether the conduct constitutes fraud.[5] It is enough that the article, with other disclosures, could put the government "on the trail" of the alleged fraud of those responsible. *Natural Gas*, 562 F.3d at 1042; *In re Pharm. Indus. AWP Litig.*, 538 F. Supp. 2d at 383 n.10. A front page article addressing AWP inflation and marketing the spread – which even Ven-A-Care admits "foretold possible additional fraud in the future" (VAC Resp. at 21) – certainly suffices.[6]

The 1996 *Barron's* article (Ex. 12) disclosed allegations that Abbott was "marketing the spread." Ven-A-Care argues that the article referred only to pharmaceuticals sold by Abbott's

[5] Ven-A-Care incompletely quotes and incorrectly applies *Minn. Ass'n of Nurse Anesthetists v. Allina Health System Corp.*, 276 F.3d 1032, 1048 (8th Cir. 2002). The court did state, in dicta, that "the independent knowledge requirement clearly serves the congressional goal of barring parasitic action, but it is worth noting that it does not bar actions based on old news, in which the relator independently discovers information already known to the public." However, *Minn. Ass'n* is distinguishable from our case in that the court determined that the relator, unlike Ven-A-Care, was *the source* of the "old news" or publicly disclosed information.

[6] Exs. 5-10 were cited for additional evidence of alleged "AWP manipulation from the late 1980s." Ven-A-Care did not address Ex. 5 (the 1989 OIG Rep.). Ex. 6 (the 1989 *Drug Store News* article) stated that AWP is inflated and "is being manipulated by many pharmaceutical manufacturers [so that] pharmacists . . . will use or substitute the product with the best AWP [i.e., marketing the spread]." Ven-A-Care merely imposes its fabricated standard that the article was a "niche market publication" that was not distributed widely enough, although Ven-A-Care admits that the magazine is marketed as the "voice of the retail drug industry." (VAC Resp. at 6.) The article was published in the "news media" and was available to the public. It is covered under 31 U.S.C. sec. 3730(e)(4)(A). *See, e.g.*, *United States ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 463 (S.D.N.Y.) (holding that "the publication of information in scholarly or scientific periodicals" constitutes news media because they "disseminate information to the public in a periodic manner" and "are as generally accessible to any other strangers to the fraud as would be a newspaper article."), *aff'd*, 53 F. App'x 153 (2d Cir. 2002); *accord In re Natural Gas Royalties Qui Tam Litig.*, 467 F. Supp. 2d 1117, 1155 (D. Wyo. 2006) (holding "media" disclosure to include "trade journal essays . . . [and] seminar papers"). Ex. 7 (the 1989 Pink Sheet) shows the VA purchasing for AWP-80+%. Ven-A-Care again argues incorrectly that the document does not qualify as "news media." Ex. 8 (the 1989 *Philadelphia Inquirer* article) reported that generic drugs were sold at AWP-50%. Ven-A-Care argues only that it does not mention Abbott or Ery. Ex. 9 (from the 1989 Congressional hearing) stated that AWPs were "significantly higher than actual costs." Ven-A-Care argues only that document does not say "fraud" and does not name Abbott or Ery. Ven-A-Care did not address Ex. 10 (1990 Drug Store News), which stated that "AWP has become an exploited figure that is often picked out of thin air by pharmaceutical manufacturers who know that as long as third-party programs continue to use AWP as a base for reimbursement, the higher the number the better their chances are of getting their products dispensed."

Hospital Products Division ("HPD") and, therefore, would not put the government on the trail of fraud with respect to oral pills, like the Erys, produced by Abbott's Pharmaceutical Products Division ("PPD"). Ven-A-Care's argument, however, ignores that the *Barron's* article *did* put the government on the trail of the alleged fraud with respect to oral pills, including the Erys. The 1997 OIG report cited the *Barron's* article as an impetus for the investigation and specifically included Abbott's Ery drugs in that investigation. (Ex. 14 at 1-2; Ex. 15 at HHD019-0064; HHD019-0072; HHD019-0073; HHD019-0074; HHD019-0339; HHD019-0551; HHD019-0561; HHD019-0563; HHD019-0571; HHD019-0574; HHD019-0772; HHD019-0777.) In addition, Ven-A-Care provides no evidence that the public would interpret the *Barron's* article as not including Abbott PPD. Ven-A-Care contradicts its own theory by arguing extensively in its motion for partial summary judgment that Abbott HPD's activities with respect to Vancomycin and solutions are relevant to PPD's conduct with respect to the Erys.

The record of discussion among OIG and state representative in 1997 about the OIG's investigation (Ex. 13) is yet another disclosure that manufacturers were "overstat[ing] AWP for marketing purposes." This is a document generated by the federal agency responsible for the investigation and disclosed to the third-party state representatives.

The 1998 OIG report (Ex. 18) noted that "manufacturers can use [AWP] as a marketing tool to gain market share." Ven-A-Care merely ignores this quote and claims, incorrectly, that the report only "pertains to the subject of Medicaid rebates." (VAC Resp. at 13.)

In the face of these public disclosures alleging that pharmaceutical manufacturers and even specifically Abbott were using AWP spreads as a marketing tool, Ven-a-Care is left only to point out that none of those specific disclosures mentioned the Ery drugs. That argument again ignores that public disclosures must be examined as a whole. Documents alleged AWP spreads on Abbott's Ery drugs and that Abbott was marketing the AWP spreads. Moreover, Ven-A-Care

cannot escape the public disclosure bar based on that argument when it did not have any evidence of Abbott marketing the Ery spreads when *it* filed its complaint. In fact, Ven-A-Care's 31 U.S.C. § 3730(b)(2) statement to the government contained no such allegation (needless to say evidence), and Ven-A-Care found no such evidence in discovery. In addition to its October 23, 2000 letter to the government (Thomas Ex. AA), which alleged only spreads, Ven-A-Care discusses a PowerPoint presentation that it made to government officials in January 2001, entitled "Drug Price Reporting Fraud By Dry Warrick, Roxanne, and Bristol Causes Injury to Medicare and Medicaid Programs."[7] This 135-page document does not even mention the Abbott Erys. Ven-A-Care also notes that it gave the McKesson Econolink database to the government, but that database certainly contains no evidence of Abbott marketing spreads. Having had a duty to disclose all of its evidence supporting its allegations and having proceeded with no evidence of Abbott marketing the spreads on the Ery drugs, Ven-A-Care cannot be heard to complain now that the public disclosures alleging that Abbott was marketing spreads did not specifically mention the Erys.[8]

II. VEN-A-CARE IS NOT AN ORIGINAL SOURCE OF THE ALLEGATIONS IN ITS COMPLAINT.

Because Ven-A-Care's allegations against Abbott were based upon public disclosures, the Court lacks subject-matter jurisdiction unless Ven-A-Care can establish that it was an original source of the disclosures. *See* 31 U.S.C. § 3730(e)(4)(A). Ven-A-Care cannot do so.

[7] Tellingly, Ven-A-Care cited only Lockwood's testimony, not the actual PowerPoint presentation. (Comb. Opp. at 10.) Abbott attaches it hereto as Ex. 29.

[8] Indeed, as Ven-A-Care learned in discovery, the public disclosures did not allege specifically that Abbott was marketing the Ery spreads because *Abbott never in fact did so*. Ven-A-Care cannot maintain standing by claiming that documents did not disclose something that never in fact happened.

A. As A Corporation, Ven-A-Care Cannot Be An Original Source.

The FCA provides that "persons" can bring cases under the Act and share in the recovery, but only "an *individual* who has direct and independent knowledge" can be deemed an original source. (Abt. Br. at 14-16; *see also* 31 U.S.C. § 3730(e)(4)(B).) As the First Circuit held when faced with a similar question of statutory interpretation, "person" includes corporations, but "individual" does not. *See In re Spookyworld, Inc.*, 346 F.3d 1, 7 (1st Cir. 2003). Thus, by the FCA's plain terms, Ven-A-Care cannot qualify as an original source.

In response, Ven-A-Care points to several cases where corporations have in fact participated in FCA actions, but not a single one of these decisions actually considers the challenge raised here by Abbott – namely, whether the statutory text of the FCA precludes corporations from being an original source. The closest is *Minn. Ass'n of Nurse Anesthetists v. Allina Health System Corp.*, 276 F.3d 1032, 1048-50 (8th Cir. 2002), in which the court found that a Minnesota unincorporated association could be a proper relator. That decision, however, was based on the theory that, under state law, the association had no legal status separate from its members and therefore had standing to bring suit on behalf of its individual member's rights. *Id.* at 1050 (drawing a contrast with "a corporation [that] has no standing to assert rights belonging to its shareholders"). The Eighth Circuit did not perform any statutory analysis of the FCA, or discuss the legal presumption that different words in the same statute have different meanings. (*See* Abt. Br. at 15-16 (collecting cases).) Ven-A-Care has offered no support, statutory or otherwise, that would permit this Court to redraft the FCA to eliminate the "individual" requirement from the original source provision. The Court should decline Ven-A-Care's invitation to engage in such judicial draftsmanship, and instead should find that, as a corporation, Ven-A-Care is not an "individual" and therefore not an original source.

B. Even If Ven-A-Care, As A Corporation, Could Qualify As An Original Source, It Is Not One Here.

Even if Ven-A-Care could overcome the statutory hurdle (and it cannot), it still does not qualify as an original source as a matter of law. There is no dispute that, in order to be an original source, the relator must have "both 'direct' and 'independent' knowledge" of the information upon which each of his or her claims is based. *In re Pharm. Indus. AWP Litig.*, 538 F. Supp. 2d at 379; *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 470-71 (2007). For knowledge to be "direct," it must be "firsthand," *United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 690 (D.C. Cir. 1997), and for it to be "independent," the knowledge must be separate from any public disclosures and "must not be derivative of the information of others," *United States ex rel. Fine v. Advanced Scis., Inc.*, 99 F.3d 1000, 1007 (10th Cir. 1996). Ven-A-Care does not and cannot claim to have *any* direct or independent knowledge supporting the allegations first made with respect to Abbott's Erys in the 2001 amended complaint.

Ven-A-Care has made clear all along that these allegations are based not on some direct knowledge or experience with the Abbott Ery drugs (Ven-A-Care has none), but rather on collateral research of secondary materials that were available to many others, such as the publishing compendia and price catalogs. (Abt. Br. at 2.) While Ven-A-Care argues that this sort of research effort is sufficient (Comb. Opp. at 28-29), the law says otherwise. In this Court's own words, "any information supporting a FCA action that Relator gained through his analysis of existing data is [ ] insufficiently direct to make him an original source." *United States ex rel. O'Keeffe v. Sverdup Corp.*, 131 F. Supp. 2d 87, 96 (D. Mass. 2001); *see also United States ex rel. Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1159 (2d Cir. 1993) ("collateral research and investigations . . . [do] not establish 'direct and independent knowledge

of the information on which the allegations are based within the meaning of § 3730(e)(4)(B)'"); *United States ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 463-64 (S.D.N.Y.) ("the 'perspective' [of relator's] members obtained by spending hundreds of hours compiling facts into a 'mosaic,'" was not sufficient to satisfy the original source requirement), *aff'd*, 53 F. Appx. 153 (2d Cir. 2002).[9] Ven-A-Care has also long argued that its knowledge as an "industry insider" (Comb. Opp. at 2) has enabled it to understand the significance of its research, but the First Circuit has finally extinguished that refrain with the recent opinion of *Ondis*, 2009 WL 3838803, at *9. Secondary research is all Ven-A-Care can offer, and it is not enough.[10]

That Ven-A-Care, a formal home infusion pharmacy, has no personal experience with the alleged spreads or marketing conduct is critical. Ven-A-Care claims to be an original source in the DOJ cases against Dey and Roxane because it was "in a position to receive, and observe the means by which Defendants communicated, the mega-spreads to providers" and was "a party to which the unlawful inducements are directed." (Comb. Opp. at 11, 27.) Regardless of the claim's merit in those cases, that most certainly is not the situation here, where Ven-A-Care had long shuttered its doors to patients by the time it discovered the Ery allegations and had never

[9] This case is quite different from the *Kennard* and *Ervin* matters cited by Ven-A-Care (VAC Comb. Opp. at 28-29). In *Kennard*, the court specifically noted that the misconduct alleged was not disclosed in any public documents and that relators "were not just assemblers of information." 363 F.3d at 1046. Similarly, the relator in *Ervin* conducted an independent investigation, filing numerous FOIA requests and interviewing witnesses, and ultimately brought forward to the government core allegations of the fraud that were not previously disclosed. 332 F. Supp. 2d at 9. In stark contrast, the allegations Ven-A-Care makes against Abbott *were* publicly disclosed, and Ven-A-Care admits that its complaint is based on no more than review of the compendia, GPO price lists, and other widely available information.

[10] Ven-A-Care's reference to "new analytical techniques" is nothing other than its use of the Econolink database, an electronic version of McKesson's price catalog, which had existed for years but which Ven-A-Care acquired in 2000 solely to find its next case; it had been out of the home infusion pharmacy business for almost half a decade by then. In addition, whether or not the price lists can be considered public is a red herring. Although those documents may count as public disclosures, Abbott's argument is based on much more. The issue is whether Ven-A-Care is an original source or whether it merely conducted collateral research from public or non-public sources.

bought, sold or submitted a claim for one of the Erys (Ex. 22 (VAC Ans. to Interrog. No. 1)) or witnessed Abbott marketing the spread on any Ery to anyone (30(b)(6) Dep. at 112:8-11; 104:12-105:4, Ex. 21). Instead, Ven-A-Care's complaint seems merely to quote directly from the earlier public disclosures. (*See, e.g.*, Complaint at ¶ 32 ("used the public fisc as a marketing tool", actively promoting government-funded 'spreads'"), Intro ("These efforts allowed Abbott to increase its profits by boosting sales for its drugs"), ¶ 3 ("Abbott actively used the inflated spreads and huge profits as a marketing tool directed at providers to promote increased sales of the Drugs").)

Ven-A-Care certainly cannot claim to be an original source of the information in Exhibit 4 (the 1987 *Lexington Herald* article). That document pre-dates any of Ven-A-Care's investigation into this area. Any claim that Ven-A-Care was an original source of Ex. 12 (*Barron's* article) is wholly unsupported. With respect to Ex. 14 (the 1997 OIG Report), Ven-A-Care argues that it "provided pricing data which underlies this report" (Opp. at 11), but that cannot establish VAC as an original source (if it is in fact attempting to argue that) when Ven-A-Care is asserting that its case involves more than just the comparison of prices (although that is all it presented to the government prior to filing the complaint). Ven-A-Care is simply not an original source.

CONCLUSION

Ven-A-Care's allegations against Abbott are based upon public disclosures for which Ven-A-Care is not the original source. For all of the reasons discussed above and in Abbott's original motion, Ven-A-Care's complaint against Abbott should be dismissed for lack of subject-matter jurisdiction under the False Claims Act's public disclosure bar.

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Respectfully submitted,

/s/ Tara A. Fumerton
James R. Daly
Eric P. Berlin
Tara A. Fumerton
JONES DAY
77 West Wacker Drive, Suite 3500
Chicago, Illinois 60601
Telephone: (312) 782-3939
Facsimile: (312) 782-8585

Counsel for Defendant Abbott Laboratories Inc.

CERTIFICATE OF SERVICE

I, Tara A. Fumerton, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES INC.'S REPLY IN SUPPORT OF MOTION TO DISMISS FOR LACK OF SUBJECT-MATTER JURISDICTION UNDER THE FALSE CLAIMS ACT'S PUBLIC DISCLOSURE BAR to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 4th day of December, 2009.

/s/ Tara A. Fumerton
Tara A. Fumerton